Summary: The Plaintiffs filed a motion for summary judgment and the Defendant filed a cross-motion for summary judgment. The Court granted the Plaintiffs' motion and denied the Defendant's motion, finding that the Administrator of the Centers for Medicare and Medicaid Services' decision was arbitrary and capricious.

Case Name: Medcenter One Health Systems, et al. v. Health & Human Services
Case Number: 1-08-cv-63
Docket Number: 38
Date Filed: 10/13/09
Nature of Suit: 151

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NORTH DAKOTA
SOUTHWESTERN DIVISION

Medcenter One Health Systems and St. Alexius Medical Center,	)	
Plaintiffs,	)	**ORDER GRANTING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND DENYING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT**
vs.	)	
Michael O. Leavitt, Secretary, Department of Health and Human Services,	)	Case No. 1:08-cv-063
Defendant.	)	

Before the Court are the Plaintiffs' motion for summary judgment filed on December 1, 2008, and the Defendant's motion for summary judgment filed on January 9, 2009. See Docket Nos. 15 and 21. On January 9, 2009, the Defendant filed a consolidated brief in response to the Plaintiffs' motion and in favor of his motion. See Docket Nos. 22 and 23. On February 10, 2009, the Plaintiffs filed a consolidated response in opposition to the Defendant's motion and in favor of their motion. See Docket Nos. 26 and 27. Oral argument was held in Bismarck, North Dakota on October 1, 2009. For the reasons set forth below, the Plaintiffs' motion for summary judgment is granted and the Defendant's motion for summary judgment is denied.

I. BACKGROUND

The facts are not in dispute. Plaintiffs Medcenter One Health Systems and St. Alexius Medical Center are hospitals located in Bismarck, North Dakota. The hospitals participate in a three-year family practice residency program operated in conjunction with the University of North Dakota School of Medicine. For accreditation purposes, a family practice residency is required to train residents in rotations outside of a hospital in non-hospital settings. To meet this requirement, Medcenter One and St. Alexius established the Family Practice Center which is located in Bismarck, North Dakota. Both hospitals train their residents at the Family Practice Center. The Family Practice Center is vital to recruiting and retaining family practice physicians to serve Bismarck and the surrounding communities.

The residency training program at the Family Practice Center was created in 1976 as a partnership between the two hospitals and the University of North Dakota School of Medicine. The operational and financial roles of the University and the hospitals with regard to the residency training program have remained the same up until and through 2004. Prior to 2005, the University was responsible for the day-to-day operational functions of resident training and the up-front aggregate costs, including faculty and staff salaries, residents' stipends and benefits, faculty supervision costs, community faculty supervision costs, and other operating expenses. The University then billed the hospitals for the costs that were not paid by other university sources, such as patient revenue. The hospitals made quarterly and year-end payments to the University, with each hospital paying the University fifty percent of the quarterly and year-end payments. The hospitals

then submitted cost reports to the Department of Health and Human Services for reimbursement of the costs incurred in training their own residents at the Family Practice Center. Prior to 1999, the hospitals were reimbursed for the direct and indirect costs that they incurred in training their own residents at the Family Practice Center.

During the years 1999, 2000, and 2001, Medcenter One and St. Alexius each claimed a share of the full-time equivalent residents that rotated through the Family Practice Center. The University billed each of the hospitals in the manner described above for the costs that were not paid by other university sources. Because the hospitals split the full-time equivalent residents that trained at the Family Practice Center and paid for the costs incurred in training their own residents, the hospitals ensured that Medicare was not overcharged and paid only once for the costs of training the full-time equivalent residents that rotated through the Family Practice Center. Nonetheless, fiscal intermediaries, acting on behalf of the Secretary for the Department of Health and Human Services, denied the hospitals Medicare reimbursement in 1999-2001, for the direct and indirect costs incurred in training their residents at the Family Practice Center. The hospitals' cost reports were adjusted in the amount of $283,115 for Medcenter One and $105,309 for St. Alexius for a total adjustment of $388,424.[1] The hospitals appealed the cost adjustments to the Department of Health and Human Services Provider Reimbursement Review Board.

[1] Medcenter One's direct and indirect costs were adjusted in the following manner: fiscal year ending December 31, 1999 – $52,860 for direct costs and $109,643 for indirect costs ($162,503 total); and fiscal year ending December 31, 2000 – $106,697 for direct costs and $13,915 for indirect costs ($120,612 total). St. Alexius's direct and indirect costs were adjusted in the following manner: fiscal year ending June 30, 2001 – $53,445 for direct costs and $51,864 for indirect costs ($105,309 total). The total costs amount to $388,424.

On July 11, 2007, the five-member Review Board conducted a hearing of the hospitals' appeal. On February 26, 2008, the Board issued a decision in favor of the hospitals. See Docket No. 12, p. 30. The Administrator of the Centers for Medicare and Medicaid Services, acting under authority delegated by the Secretary, exercised his discretion and reviewed the Board's decision. On April 25, 2008, the Administrator issued a decision in which he affirmed the fiscal intermediaries' decision and reversed the Board's decision, finding that the hospitals failed to meet the statutory and regulatory requirements for reimbursement of direct and indirect costs for residency training. See Docket No. 12, p. 2. On June 27, 2008, the hospitals filed a complaint in federal district court for judicial review of the agency decision.

The parties have each filed summary judgment motions. There are no factual issues in dispute. The Plaintiffs contend that the Administrator erred in reversing the Provider Reimbursement Review Board and affirming the fiscal intermediaries' disallowance of residents' rotations at the Family Practice Center for years 1999, 2000, and 2001. The Plaintiffs contend that the Administrator retroactively applied the Secretary's 2003 interpretation of the Medicare Act to disallow the residents' rotations and, therefore, the final decision of the Secretary was arbitrary and capricious. The Secretary contends that the Plaintiffs did not meet the requirements under the Medicare Act because they did not have a written agreement to indicate which facility, namely, Medcenter One, St. Alexius, or the Family Practice Center, would bear all or substantially all of the costs of the residency training program. In addition, the Secretary contends that even if the Court finds that the Plaintiffs satisfied the written agreement requirement under the Medicare Act, the Administrator's application of the 2003 interpretation of the Medicare Act was not a retroactive

application of the law, but rather was a clarification of the policies that were in effect for the years in dispute.

II. STANDARD OF REVIEW

The Court has jurisdiction to hear the action pursuant to 42 U.S.C. § 1395oo(f), which incorporates the review standards of the Administrative Procedure Act (APA), 5 U.S.C. § 701 et seq. 5 U.S.C. § 706 governs the scope of judicial review and provides, in part:

> To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall –
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> (2) hold unlawful and set aside agency action, findings, and conclusions found to be –
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> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
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> (B) contrary to constitutional right, power, privilege, or immunity;
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> (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;
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> (D) without observance of procedure required by law;
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> (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or
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> (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

5 U.S.C. §706(2). "Because this is a deferential standard, 'the orderly functioning of the process of review requires that the grounds upon which the administrative agency acted be clearly disclosed and

adequately sustained.'" Gatewood v. Outlaw, 560 F.3d 843, 846 (8th Cir. 2009) (quoting SEC v. Chenery Corp., 318 U.S. 80, 94 (1943)).

Judicial review of an agency's construction of a statute which it administers is generally governed by Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984). The court must review the agency's construction of the statute and determine whether the intent of Congress is clear and, if so, give effect to the unambiguously expressed intent of Congress. If the intent of Congress is not clear, the court must determine whether the agency's interpretation is based on a permissible construction of the statute. The United States Supreme Court has said, "We have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer, and the principle of deference to administrative interpretations." Id. at 844.

The court must defer to the agency's interpretation of its own regulations. Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994). Broad deference is especially accorded when, as here, the regulation concerns "a complex and highly technical regulatory program." Pauley v. BethEnergy Mines, Inc., 501 U.S. 680, 697 (1991). "A reviewing court should not reject a reasonable administrative interpretation even if another interpretation may also be reasonable." Call A Nurse, Inc. v. Shalala, 59 F. Supp. 2d 938, 942 (E.D. Mo. 1999) (citing Creighton Omaha Reg'l Health Care Corp. v. Bowen, 822 F.2d 785, 789 (8th Cir. 1987)).

The APA grants federal courts the power to set aside an agency's action that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. Anderson v. Farm Serv. Agency of the United States Dep't of Agric., 534 F.3d 811, 814 (8th Cir. 2008). A decision is arbitrary and capricious if "the agency has relied on factors which Congress has not intended it to

consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." In re Operation of Missouri River Sys. Litig., 421 F.3d 618, 628 (8th Cir. 2005) (citing Cent. South Dakota Coop. Grazing Dist. v. Sec'y of the United States Dep't of Agric., 266 F.3d 889, 894 (8th Cir. 2001)).

III. LEGAL DISCUSSION

The Court's review is limited to a determination of whether the agency's determination was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. "This narrow review entails a 'searching and careful' de novo review of the administrative record presented to determine 'whether the decision was based on a consideration of relevant factors and whether there has been a clear error of judgment.'" Rosenau v. Farm Serv. Agency, 395 F. Supp. 2d 868, 872 (D.N.D. 2005) (quoting Downer v. United States, 97 F.3d 999, 1002 (8th Cir. 1996)).

Where the terms of a statute are clear and straightforward, judicial inquiry is complete and the legislative history should not be considered. United States v. Vig, 167 F.3d 443, 448 (8th Cir. 1999). It is well-settled that where a statute is ambiguous, the court may look at the statute's legislative history.

A. OVERVIEW OF MEDICARE

The Medicare program,[2] Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq., was established to provide health insurance to the aged and the disabled. Medicare Part A serves as

[2] The Medicare program is also known as the "Medicare Act."

hospital insurance and covers the costs of hospital, related post-hospital, home health services, and hospice care. 42 U.S.C. § 1395c et seq. Medicare Part B serves as supplementary medical insurance and covers the costs of medical and other health services. 42 U.S.C. § 1395j et seq. The Medicare program is run and administered by the federal government. The Centers for Medicare and Medicaid Services (CMS), formerly known as the Health Care Financing Administration (HCFA), is the federal agency within the Department of Health and Human Services charged with administering the Medicare program. CMS contracts out its payment and audit functions under the Medicare program to third parties known as "fiscal intermediaries." The medical provider submits a cost report at the end of the fiscal year to a fiscal intermediary. The fiscal intermediary audits the cost report and issues a Notice of Program Reimbursement which specifies the amount of reimbursement due to the provider and explains any adjustments. Bethesda Hosp. Ass'n v. Bowen, 485 U.S. 399, 401 (1988). In this case, the fiscal intermediaries that acted on behalf of the Secretary to audit the cost reports of Medcenter One and St. Alexius are Noridian Administrative Services and Blue Cross Blue Shield Association.

A medical provider may appeal the fiscal intermediary's final determination to the Provider Reimbursement Review Board. The Review Board may affirm, modify, or reverse the fiscal intermediary's decision. The Secretary of the Department of Health and Human Services, through the Administrator, may review the Board's determination, either sua sponte or on request of the medical provider. The medical provider may seek judicial review of the Secretary's final determination in a federal district court.

This case involves the issue of whether Medcenter One and St. Alexius are entitled to reimbursement under the Medicare Act for the direct and indirect costs the hospitals incurred in

training medical residents at the Family Practice Center during the years 1999, 2000, and 2001. Pursuant to Part A of the Medicare program, a hospital may be reimbursed for the direct (graduate medical education) and indirect (indirect graduate medical education) costs that are incurred in training residents and have been covered and paid for as "inpatient hospital services." See 42 U.S.C. §§1395x(b)(6) (2000) and 1395x(q) (2000); 42 C.F.R. §§ 415.200 (2000) and 415.206 (2000). Graduate medical education (GME) costs include "residents' salaries and fringe benefits (including travel and lodging where applicable) and the portion of the cost of teaching physicians' salaries and fringe benefits attributable to direct graduate medical education." 42 C.F.R. § 413.86(b)(3) (2000); see Univ. of Iowa Hospitals and Clinics v. Shalala, 180 F.3d 943, 947 (8th Cir. 1999) ("Costs associated with graduate medical education include the salaries and benefits paid to interns and residents, the salaries paid to teaching physicians for the time spent supervising interns and residents, and various overhead and indirect costs."). Medicare reimbursement for a teaching hospital's GME cost is based on a hospital-specific rate per resident and the hospital's number of full-time equivalent residents in training. 42 U.S.C. § 1395ww(h) (2000). Indirect graduate medical education (IME) expenses include "'the additional tests and procedures ordered by residents as well as the extra demands placed on other staff as they participate in the educational processes.'" St. Mary's Hosp. of Rochester, Minn. v. Leavitt, 416 F.3d 906, 909 (8th Cir. 2005) (quoting H.R. Rep. No. 98-25(I), at 140 (1983)). Medicare reimbursement for IME costs is calculated from a "formula [] derived from a statistical analysis of teaching hospitals' costs compared to non-teaching hospitals' costs that takes into account the ratio of residents and interns to beds . . . ." St. Mary's Hosp. of Rochester, Minn., 416 F.3d at 909.

Medicare reimburses the medical provider for the direct and indirect costs incurred in training residents based on the number of full-time equivalent residents. Historically, for GME and IME purposes, a resident's time was counted towards full-time equivalency for the time spent training in the hospital. In 1986, Congress amended the Medicare regulations to allow a hospital to count all of a resident's training time, regardless of the setting, towards the hospital's full-time equivalent resident count for GME costs. H.R. Rep. No. 99-727, at 70 (1986). In the House Report, Congress stated, "The Committee bill would change the current regulations by providing that all of the time that a resident spends in activities related to patient care is to be counted towards full-time equivalency, without regard to the setting in which those activities take place, so long as the hospital is incurring costs for that resident's training."[3] H.R. Rep. No. 99-727, at 70.

In 1997, Congress amended the Medicare reimbursement statute to allow a hospital to count all of a resident's training time, regardless of the setting, towards the hospital's full-time equivalent resident count for IME costs. See 42 U.S.C. § 1395ww(d)(5)(B)(iv) ("Effective for discharges occurring on or after October 1, 1997, all the time spent by an intern or resident in patient care activities under an approved medical residency training program at an entity in a nonhospital setting shall be counted towards the determination of full-time equivalency if the hospital incurs all, or substantially all, of the costs for the training program in that setting."). Accordingly, the Medicare reimbursement statute for the years at issue provided that all of the time a resident spends in training under an approved medical residency training program, regardless of the setting, shall be counted

[3] In Medicare Program; Changes in Payment Policy for Direct Graduate Medical Education Costs, 54 Fed. Reg. 40,286 (Sept. 29, 1989), the Secretary promulgated rules and regulations in accordance with Congress's change to allow a hospital to count the time that a resident spends in a non-hospital setting towards the hospital's full-time equivalent resident count for GME costs.

towards the determination of full-time equivalent resident counts so long as (1) the resident is involved in patient care activities and (2) the hospital incurs "all, or substantially all, of the costs for the training program" in the non-hospital setting. 42 U.S.C. §§ 1395ww(d)(5)(B) (1999, 2000, and 2001) and 1395ww(h)(4)(E) (1999, 2000, and 2001). In addition to the two statutory requirements for counting a resident's non-hospital training time for GME and IME payments, the Secretary's regulations imposed an additional administrative requirement, namely, that the hospital have a written agreement with the non-hospital site. See 42 C.F.R. § 413.86(f)(4) (2000); see also 42 C.F.R. § 412.105(f)(1)(ii)(C) (2000) (applying the standard set forth under 42 C.F.R. § 413.86(f)(4) with regard to IME costs).

The primary issue before the Court is whether the Administrator's determination that the Plaintiffs had not incurred all or substantially all of the costs for the residency training program at the Family Practice Center during the years 1999, 2000, and 2001 was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. The Plaintiffs contend that the Administrator's decision was arbitrary, capricious, contrary to law, and in excess of statutory authority because: (1) the Administrator applied the Medicare Act retroactively to deny the Plaintiffs' benefits; (2) the Administrator's decision permits an invalid agency action without the observance of legally required procedures; (3) the Administrator's decision is inconsistent with the plain language of the Medicare Act; and (4) the Administrator's decision ignores the substantial evidence and the law demonstrating that the Plaintiffs met the requirements under the Medicare Act. The Secretary contends that his interpretation of the applicable statutes and regulations is reasonable and entitled to deference.

B. STATUTORY AND REGULATORY REQUIREMENTS

As previously stated, the statutory and regulatory provisions which govern GME payments to a hospital for the time that a resident spends in residency training are 42 U.S.C. § 1395ww(h)(4)(E) (2000) and 42 C.F.R. § 413.86(f)(4) (2000). The statutory and regulatory provisions which govern IME payments to a hospital for the time that a resident spends in a training program are 42 U.S.C. § 1395ww(d)(5)(B) (2000) and 42 C.F.R. § 412.105(f)(1)(ii)(C) (2000).

42 U.S.C. § 1395ww(h)(4)(E) reads as follows:

> Such rules shall provide that only time spent in activities relating to patient care shall be counted and that all the time so spent by a resident under an approved medical residency training program shall be counted towards the determination of full-time equivalency, without regard to the setting in which the activities are performed, if the hospital incurs all, or substantially all, of the costs for the training program in that setting.

42 U.S.C. § 1395ww(h)(4)(E) (2000) (emphasis added). Congress did not impose any additional or other requirements for hospitals seeking payment for IME costs. Therefore, the statutory requirements for a hospital seeking both GME and IME costs for the time that a resident spends in a training program are found under 42 U.S.C. § 1395ww(h)(4)(E).

In addition to the two statutory requirements under 42 U.S.C. § 1395ww(h)(4)(E), the Secretary imposed an additional requirement, namely, a requirement that the hospital and non-hospital site have entered into a written agreement. 42 C.F.R. § 413.86(f)(4) (2000) (emphasis added) reads as follows:

> (f)(4) For portions of cost reporting periods occurring on or after January 1, 1999, the time residents spend in nonprovider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs may be included in determining the number of [full-time equivalent] residents in the calculation of a hospital's resident count if the following conditions are met:

(i) The resident spends his or her time in patient care activities.

(ii) The written agreement between the hospital and the nonhospital site must indicate that the hospital will incur the cost of the resident's salary and fringe benefits while the resident is training in the nonhospital site and the hospital is providing reasonable compensation to the nonhospital site for supervisory teaching activities. The agreement must indicate the compensation the hospital is providing to the nonhospital site for supervisory teaching activities.

(iii) The hospital must incur all or substantially all of the costs for the training program in the nonhospital setting in accordance with the definition in paragraph (b) of this section.

42 C.F.R. § 412.105(f)(1)(ii)(C) incorporates the same requirements described in 42 C.F.R. § 413.86(f)(4) for reimbursing hospitals for IME costs.[4] The statutes do not define "all or substantially all." The regulations define "all or substantially all" as "the residents' salaries and fringe benefits (including travel and lodging where applicable) and the portion of the cost of teaching physicians' salaries and fringe benefits attributable to direct graduate medical education." 42 C.F.R. § 413.86(b)(3) (2000). Neither the statutes nor the regulations define the term "program."

1) PATIENT CARE ACTIVITIES

Both the statutes and the regulations require that the residents claimed by the Plaintiffs for the years 1999, 2000, and 2001 spent their time in patient care activities. The parties do not dispute that the residents claimed by the Plaintiffs as full-time equivalent residents for the years 1999, 2000,

[4] 42 C.F.R. § 412.105(f)(1)(ii)(C) provides: "Effective for discharges occurring on or after October 1, 1997, the time spent by a resident in a nonhospital setting in patient care activities under an approved medical residency training program is counted towards the determination of full-time equivalency if the criteria set forth at § 413.86(f)(4) are met."

and 2001 spent their time in patient care activities. Therefore, the Court will not address this requirement.

2) WRITTEN AGREEMENT

42 C.F.R. § 413.86(f)(4) (2000) and 42 C.F.R. § 412.105(f)(1)(ii)(C) (2000) require that the hospital and the non-hospital provider have entered into a written agreement which indicates that the hospital will assume financial responsibility for the cost of the resident's salary and fringe benefits while the resident is training in the non-hospital site, and that the hospital is providing reasonable compensation to the non-hospital site for supervisory teaching activities. In the 1998 revised regulations, the Secretary explained that:

> We proposed that, in order for a hospital to include residents' training time in a nonhospital setting, the hospital and the nonhospital site must have a written contract which indicates the hospital is assuming financial responsibility for, at a minimum, the cost of residents' salaries and fringe benefits (including travel and lodging expenses where applicable) and the costs for that portion of teaching physicians' salaries and fringe benefits related to the time spent in teaching and supervision of residents.
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> The contract must indicate that the hospital is assuming financial responsibility for these costs directly or that the hospital agrees to reimburse the nonhospital site for such costs.

Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1999 Rates, 63 Fed. Reg. 40,954, 40,989 (July 31, 1998).

The Secretary contends that the 1998 revised regulations provided notice to the Plaintiffs that, in order for a hospital to be reimbursed from Medicare for GME or IME costs for the time that a resident spends in a residency training program, there must be a contract between the hospital and the non-hospital site which specifies that the hospital incurred the financial responsibility for the

costs of the resident's salaries and fringe benefits and the costs for that portion of teaching physicians' salaries and fringe benefits related to the time spent teaching and supervising the resident. The revised rules were codified at 42 C.F.R. § 413.86(f)(4) (1998).

In the final decision rendered by the agency, the Administrator of the Department of Health and Human Services, in a footnote, addressed whether the Plaintiffs satisfied the written agreement requirement of 42 C.F.R. § 413.86(f)(4). The Administrator stated as follows:

> The Administrator notes that, up to the time of the filing of position papers, the Intermediary maintained that the Providers did not meet the documentation requirement of a written agreement. The Intermediary stated in its position paper that the Providers "may" have met the documentation requirements through submissions made in its appeal. While that issue was not further addressed before the Board, the Administrator finds that the documents at P-7 do not, on their face, appear to set forth all the requirements of a written agreement of 42 CFR 413.86. The Statement of Agreement was dated 1995, prior to the cost years at issue, and was to June 30, 1997. It is only followed up with a letter from the Medical School to the Providers, dated July 23, 1997, recording that "[o]perating deficits will be covered by the hospital to the extent that they are incurred, consistent with the agreed upon goal and sound practices. This particular agreement will last three years." Neither document indicates the compensation the hospital is providing for resident/supervisory teaching activities and, on its face, is agreeing to incur the costs for operating deficits, not the costs incurred for the training program. See, e.g., State of Agreement at 2 ("The Consortium shall be fiscally responsible for the Program only to the level no greater than the per resident actual reimbursement from the Medicare or all payer pool"; "Program shall be responsible for the Program expenses as much as possible from the generation of Patient revenue, Grants & Contracts revenue, State Appropriations from [the medical school], and other revenue produced by Faculty, Residents or Staff . . . .")

See Docket No. 12, p. 11 n. 16.

The Administrator's decision primarily addressed whether the Plaintiffs met the "all or substantially all" requirement under the statutes and regulations. The Secretary now devotes considerable attention to the issue of whether the Plaintiffs satisfied the written agreement requirement under the regulations, and contends that the Plaintiffs have failed to provide sufficient

evidence to satisfy the written agreement requirement. The Plaintiffs contend that the Secretary is barred from raising the issue of the written agreement requirement at this stage of the litigation because the Plaintiffs were unable to present evidence of a written agreement at the administrative level.

The fiscal intermediaries initially contended that the Plaintiffs failed to satisfy the written agreement requirement of 42 U.S.C. § 413.86(f)(4). However, on the eve of the scheduled hearing before the Provider Reimbursement Review Board, the fiscal intermediaries conceded that the Plaintiffs met the written agreement requirement. The "Provider Reimbursement Review Board Decision" clearly states that the fiscal intermediaries conceded the Providers (the hospitals) met the written agreement requirements of 42 C.F.R. § 413.86(f)(4). See Docket No. 12, p. 33. The Plaintiffs argue that the Review Board relied on the fiscal intermediaries' concession and, therefore, the Board did not accept evidence of an agreement. In addition, the Administrator, despite noting in a footnote that the documents presented by the Plaintiffs do not appear to satisfy the written agreement requirement, made his ruling solely on the issue of whether the Plaintiffs met the "all or substantially all" statutory and regulatory requirement.

"The APA requires that courts review the entire record or those parts cited by a party. Thus, the court's review is limited to the administrative record that was before the agency decisionmaker." Nat'l Wildlife Fed'n v. Harvey, 574 F. Supp. 2d 934, 947 (E.D. Ark. 2008). The Court finds that the issue of whether the Plaintiffs met the written agreement requirements under 42 C.F.R. § 413.86(f)(4) is not a relevant issue before the Court in this dispute. The fiscal intermediaries, as agents of the Department of Health and Human Services, conceded the Plaintiffs met the written agreement requirements. The Provider Reimbursement Review Board acknowledged in its order that

compliance with the written agreement requirements was not at issue or in dispute. The Administrator gave the matter only passing notice in a footnote. The issue was obviously of no importance whatsoever nor did it form a basis for the Administrator's final decision. Therefore, this Court need not address the matter. The administrative record before the agency decisionmaker and this Court is clear – the Department of Health and Human Services has conceded that the hospitals met the written agreement requirements of 42 C.F.R. § 413.86(f)(4). Any decision by the agency to the contrary is implausible.

3) "ALL OR SUBSTANTIALLY ALL" REQUIREMENT

The final statutory and regulatory requirement is that a hospital must incur all or substantially all of the costs for the training program in the non-hospital setting. The Administrator's decision focused entirely on whether the Plaintiffs satisfied this requirement. Noting that neither 42 U.S.C. § 1395ww(h)(4)(E) nor 42 C.F.R. § 413.86(f)(4) define "program," the Administrator determined that the term refers to an "approved medical residency training program":

> While the statute and regulation does not define "program," it does define "approved residency training program," which may reasonably be concluded to encompass the use of the term "program." In particular, Section 1886(h)(5)(A)[5] explains that the term "approved medical residency training program means a residency or other post-graduate medical training participation in which may be counted towards certification in a specialty or sub-specialty, and includes formal post-graduate training programs in geriatric medicine approved by the Secretary." In addition, the regulation at 42 C.F.R. § 413.86(b) sets forth a similar definition of the term "approved residency program."
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> . . .

[5] Section 1886(h)(5)(A) refers to Section 1886(h)(5)(A) of the Social Security Act, as amended 42 U.S.C. § 1395ww(h)(5)(A).

> The Administrator finds that the controlling statutory language at sections 1886(h)(4)(E)[6] and 1886(d)(5[])](B)(iv)[7] plainly refer to an "approved medical residency program" in the same paragraph that requires the hospital to "incur all or substantially all["] of the costs for the "training program in that setting." Consequently, the costs of the "training program in that setting" are the costs of the "approved medical residency program," a term that is defined in the statute and regulation. In this instance, the "approved medical residency program" at issue is the family practice residency program operated by the University of North Dakota Medical School in conjunction with the two Providers at the non-hospital setting.

See Docket No. 12, pp. 8-9, 11-12.

42 U.S.C. § 1395ww(h)(4)(E) (2000) requires that "all the time so spent by a resident under an approved medical residency training program shall be counted towards the determination of full-time equivalency . . . if the hospital incurs all, or substantially all, of the costs for the training program in that setting." Congress did not define the term "program." Nor does Congress define the term "all or substantially all." However, the regulations define "all or substantially all" as "the residents' salaries and fringe benefits (including travel and lodging where applicable) and the portion of the cost of teaching physicians' salaries and fringe benefits attributable to direct graduate medical education." 42 C.F.R. § 413.86(b)(3) (2000).

The parties offer differing definitions for "program." The Secretary contends that "program" refers to an "approved medical residency training program" and, therefore, a hospital must incur all or substantially all of the costs for the entire residency training program before it can be reimbursed under the Medicare Act for residency training. The Plaintiffs contend that there is nothing on the face of 42 U.S.C. § 1395ww(h)(4)(E) to suggest that Congress intended the terms "approved medical

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[6] Section 1886(h)(4)(E) refers to Section 1886(h)(4)(E) of the Social Security Act, as amended 42 U.S.C. § 1395ww(h)(4)(E).

[7] Section 1886(d)(5)(B)(iv) refers to Section 1886(d)(5)(B)(iv) of the Social Security Act, as amended 42 U.S.C. § 1395ww(d)(5)(B)(iv).

residency training program" and "program" to be interchangeable. As a result, the Plaintiffs argue that "program" has a distinct and separate meaning. The Court finds that the parties have presented different, but rational interpretations of 42 U.S.C. § 1395ww(h)(4)(E).

When a statute is found to be ambiguous, the Court may look to the legislative history of the statute for further guidance of Congress's intent. In H.R. Rep. No. 99-727, at 70 (1986) (emphasis added), Congress stated:

> Under current Medicare regulations, a resident's time spent in an ambulatory setting is counted towards full-time equivalency only if the setting is, organizationally, part of the hospital where the resident's training program is located. If the resident is assigned to a free-standing setting, such as a family practice center or clinic or a free-standing ambulatory surgery center, no Medicare payments are allowed for the time spent there. [Since] it is difficult to find sufficient other sources of funding for the costs of such training, assignments to these settings are discouraged. It is the Committee's view that training in these settings is desirable, because of the growing trend to treat more patients out of the inpatient hospital setting and because of the encouragement it gives to primary care.
>
> The Committee bill would change the current regulations by providing that all of the time that a resident spends in activities related to patient care is to be counted towards full-time equivalency, without regard to the setting in which those activities take place, so long as the hospital is incurring costs for that resident's training.

The legislative history expressly reveals Congress's intent to encourage residency training in non-hospital settings. The legislative history is instructive, but not dispositive, of whether Congress intended for a hospital to incur all or substantially all of the costs for the entire training program, or to incur all or substantially all of the costs for training only the residents claimed on its cost reports. As a result, the Court will examine whether the relevant regulations provide further guidance. 42 C.F.R. § 413.86(f)(4)(iii) (2000) provides, "The hospital must incur all or substantially all of the costs for the training program in the nonhospital setting . . . ." The "all or substantially all"

requirement of 42 C.F.R. § 413.86(f)(4) is virtually identical to that of 42 U.S.C. § 1395ww(h)(4)(E). The regulation does not resolve which of the competing interpretations is correct. Accordingly, the Court will examine the policy that was in effect during the years in question and relied on by the Administrator in making his determination.

a) 1998 REVISED REGULATIONS

The Administrator determined that the controlling policy in effect during the years in question was found in the 1998 revised regulations: Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1999 Rates. The 1998 revised regulations clarified the definition of "all or substantially all":

> We proposed that, in order for a hospital to include residents' training time in a nonhospital setting, the hospital and the nonhospital site must have a written contract which indicates the hospital is assuming financial responsibility for, at a minimum, the cost of residents' salaries and fringe benefits (including travel and lodging expenses where applicable) and the costs for that portion of teaching physicians' salaries and fringe benefits related to the time spent in teaching and supervision of residents.
>
> The contract must indicate that the hospital is assuming financial responsibility for these costs directly or that the hospital agrees to reimburse the nonhospital site for such costs.

Medicare Program, 63 Fed. Reg. at 40,989. The Secretary contends that the 1998 revised regulations set forth the policy that one entity, either hospital or qualified non-hospital provider, must incur all or substantially all of the costs for the full complement of residents training at a residency training program in order to be reimbursed under the Medicare Act. In other words, the Secretary contends that either the hospital or the qualified non-hospital provider must pay for all or substantially all of

the costs for the entire residency training program. The Secretary argues that the 1998 revised regulations provided notice to the Plaintiffs that hospitals were prohibited from splitting the costs of a residency training program. The Secretary cites the following provisions of the 1998 revised regulations:

> Comment: Several commenters were concerned that if neither the hospital or nonhospital site incurs "all or substantially all" of the costs, neither setting would receive payment even though each entity incurs a portion of the training costs. One commenter suggested that there will be difficulty allocating costs under our proposed definition of "incurring costs" and stated that we should encourage affiliations and provide simpler and clearer guidance for institutions.
>
> Response: Under this final rule, an entity [hospital or nonhospital site] must incur "all or substantially all" of the costs to receive payments for the time the resident spends in the nonhospital site. Since we do not conduct cost-finding to determine who bears "all or substantially all" of the graduate medical education costs, we are generally dependent on hospital and non-hospital provider agreements to determine who bears them. As stated earlier in this final rule as well as in the proposed rule, we do not believe it would be administratively feasible to apportion payments appropriate to the hospital and nonhospital site in situations where neither the hospital or nonhospital site agree on who incurs "all or substantially all" of the costs. We must also consider the statutory prohibition on double payments in these situations. Furthermore, although it may be appropriate to provide payment for GME costs where the nonhospital site incurs only a portion of the training costs, we do not believe it would be equitable to allow a nonhospital site to be paid where it was incurring only a potion of the costs but only allow payment to a hospital when it incurs "all or substantially all" of the costs.
>
> In response to the commenter who suggested that we should encourage "affiliations," we believe the revised definition of "all or substantially all" of the costs provides incentives for hospitals and nonhospital sites to reach agreement with regard to financial arrangements for training in nonhospital sites to avoid the situation where neither entity receives payment for GME.

Medicare Program, 63 Fed. Reg. at 40,995. The Secretary states the following: "the Secretary, in the implementing regulations (63 Fed. Reg. 40,954 (July 31, 1998)), asserted that it was not administratively feasible to apportion payments for GME/IME payments. It was not administratively

feasible because the agency does not conduct cost finding to determine who bears all or substantially all of the required costs." See Docket No. 22.

The Plaintiffs contend that the Secretary's reliance on 63 Fed. Reg. 40,954 (July 31, 1998) is disingenuous because the cited provisions relate to qualified non-hospital providers,[8] not hospitals:

> From the beginning, this case has always involved Medicare payments to hospitals and more specifically, the interpretation and application of the requirements for *hospitals* to count a resident's nonhospital training time toward the *hospitals'* [full-time equivalent] count pursuant to sections 42 U.S.C. §§ 1395ww(h)(4)(E) and 1395ww(d)(5)(B)(iv) (sections 1886(h)(4)(E) and 1886(d)(5)(B) of the [Social Security Act]) and 42 C.F.R. §§ 413.86(f) and 412.105. *See* [Administrative Record] at 3 at n.2 (Administrator's decision identifying the governing statutes as [Social Security Act] §§ 1886(h)(4)(E) and (d)(5)(B)); *see also* 42 C.F.R. § 413.86(a)(2) (stating "[t]his section [including 413.86(f)] applies to Medicare payments to hospitals and hospital-based providers.")
>
> The discussion upon which the Secretary relies, however, arises under 42 U.S.C. § 1395ww(k) (section 1886(k) of [the Social Security Act]) and regulations promulgated at 42 C.F.R. § 405.2468, which govern Medicare payments to *qualified nonhospital providers, such as Federally Qualified Health Centers or Rural Health Clinics*. *See* 63 Fed. Reg. at 40,987 (noting that the policies referenced by the Secretary related to payments to *qualified nonhospital settings*). As such, it is disingenuous at best for the Secretary to suggest that these sections and attendant discussions have any legal application to this case.

See Docket No. 26 (emphasis in original). The Family Practice Center is not a qualified non-hospital provider under 42 U.S.C. § 1395ww(k).

Moreover, the Plaintiffs argue that the statutes relating to qualified non-hospital providers are more stringent than those relating to hospitals. See Docket No. 26 (citing Medicare Program, 63 Fed. Reg. at 40,994). The relevant portions of the Federal Register which describe the differences between the statutes are as follows:

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[8] 42 U.S.C. § 1395ww(k) defines "qualified nonhospital providers" as a federally qualified health center, a rural health clinic, Medicare+Choice organizations, and any other providers the Secretary deems appropriate.

> Since its inception in 1965, Medicare has provided payment only to hospitals for the costs of graduate medical education (GME) training. The [Balanced Budget Act of 1997] allows for direct GME payment to qualified nonhospital providers to encourage training of future physicians in nonhospital settings. Under Section 1886(k) of the Act, as added by section 4625 of the [Balanced Budget Act of 1997], the Secretary is now authorized, but not required, to pay qualified nonhospital providers for the direct costs of GME training.
>
> . . .
>
> Comment: Several commenters suggested that we initiate demonstration projects addressing payment for GME in nonhospital sites. One commenter suggested that we analyze our proposed revision to "all or substantially all" of the costs through a demonstration project before implementing the changes on a nationwide basis. Such a demonstration project would indicate whether the proposed change would encourage or discourage training in nonhospital sites. Another commenter suggested that our proposed policy may adversely affect many GME programs and should be tested prior to being implemented on a national basis.
>
> Response: Congress established a provision in the [Balanced Budget Act of 1997] authorizing the Secretary to provide payment to nonhospital sites and we do not believe a demonstration project is necessary. Furthermore, since this policy is more stringent than existing regulations, we are doubtful that hospitals would participate voluntarily in a demonstration project.

Medicare Program, 63 Fed. Reg. at 40,986, 40,994 (emphasis added). The Court finds that in the 1998 revised regulations, the Secretary concedes that the regulations relating to qualified non-hospital providers are more stringent than those relating to hospitals.

The 1998 revised regulations indicate that, for the first time, the Secretary allowed qualified non-hospital providers to be reimbursed for the direct costs of graduate medical education. Even though the Secretary stated in the revised regulations that the "direct costs" for qualified non-hospital providers are comparable to the direct costs for hospitals, direct costs for qualified non-hospital providers may include other elements as well:

> Our definition of "direct costs" for qualified nonhospital providers is comparable to the direct costs that are included in the per resident amount paid to hospitals under

> section 1886(h) of the Act. At present, there is limited information regarding the actual costs of training residents in nonhospital sites. After we gain experience providing direct GME payments to qualified nonhospital providers and have reviewed the GME costs separately reported by these qualified nonhospital providers, we may revise the definition of "direct costs." We solicited comments on other elements that may constitute direct costs of GME in the qualified nonhospital provider that can be identified, reported, and verified as directly attributable to GME activities through the cost reporting process. We were interested in comments on whether we should include other costs in the definition of "direct costs" for qualified nonhospital providers and on the administrative feasibility of identifying the GME portion of those costs.

Medicare Program, 63 Fed. Reg. at 40,987. Because of the uncertainty in assessing exactly what constitutes "direct costs" for qualified non-hospital providers, and because hospitals and qualified non-hospital providers often share the costs of training residents, the Secretary found it unfeasible to apportion costs between the hospital and the qualified non-hospital provider:

> One of our major concerns in developing policies for paying qualified nonhospital providers for the direct costs of GME is the administrative feasibility of determining the amount of direct costs incurred by the qualified nonhospital provider. It is our understanding that, currently, hospitals and nonhospital sites often share, to varying degrees, the costs of training residents in the nonhospital site. Because of the difficulty in apportioning costs between the hospital and the nonhospital for the training in the nonhospital site, we believe that it is not administratively feasible to pay both the hospital and the nonhospital site for the cost of training in the nonhospital site. We have been unable to devise a method for accurately apportioning costs between the two entities.
>
> Furthermore, the potential for both the hospital and the qualified nonhospital provider to be paid for the same direct GME expenses poses a significant problem for complying with section 1886(h)(3)(B) of the Act, as amended by the [Balanced Budget Act of 1997], which specifically prohibits double payments. Under this provision, the Secretary shall reduce the hospital's GME payment (the "aggregate approved amount") to the extent we pay the qualified nonhospital provider for GME costs under section 1886(k) of the Act. Consequently, our policy must ensure that Medicare does not pay two entities for the same training time in the nonhospital site.
>
> Given that the hospital's per resident amount can include, but is not necessarily based on the costs of training in the nonhospital site, we were not able to devise an equitable way of reducing the hospital's per resident payment to reflect payments

> made under section 1886(k) of the Act. It may not be equitable to subtract the exact amount of payment made to the qualified nonhospital provider from the hospital's per resident payment because the payment made to the nonhospital site may be unrelated to the hospital's per resident amount. We believe that the residents' salaries, teaching physicians' salaries, and overhead costs for the nonhospital setting will constitute a different proportion of the total GME costs in the nonhospital setting as compared with the hospital setting. Rather, it may be more equitable to determine the proportion of costs incurred by each entity and reduce the hospital's per resident payment by the proportion of GME costs incurred by the nonhospital site; however, since specific components of the per resident amount were not identified in the hospital's GME base year (1984), we cannot accurately determine the appropriate amount to reduce the current year hospital per resident payment amount. Moreover, to reduce the hospital's GME payments based solely on the amount paid to the qualified nonhospital provider could result in inequitable payments to the hospital, which has ongoing costs even when the resident is training in the nonhospital site. In fact, it could leave the hospital at risk of receiving no payment for the GME costs it has incurred.
>
> In order to encourage training in nonhospital sites, it is important to develop a policy that, while providing payment to qualified nonhospital providers, would also be equitable to hospitals. We believe that paying only the qualified nonhospital provider for the training costs could result in hospitals choosing not to rotate their residents to the nonhospital site. We have been unable to devise an equitable and accurate method for dividing the GME payment for training in the nonhospital site if neither the hospital, nor the nonhospital site incurs "all or substantially all" of the costs. As such, we solicited comment on possible methods for allocating the GME payments for training in the nonhospital site where neither the hospital nor the qualified nonhospital provider agrees who is incurring "all or substantially all" of the costs for the training program. We believe that the policies discussed below are equitable to both hospital and qualified nonhospital providers and will achieve Congress' objective of encouraging and supporting training in the nonhospital setting.

Medicare Program, 63 Fed. Reg. at 40,987-88.

The Court finds that the 1998 revised regulations, found in 63 Fed. Reg. 40,954 (July 31, 1998), set forth the proposed rules for Medicare reimbursement to qualified non-hospital providers for GME costs. The Family Practice Center is not a qualified non-hospital provider. In the 1998 revised regulations, the Secretary noted there is limited information regarding the actual costs of training residents in qualified non-hospital providers. Therefore, the Secretary was unsure as to what

costs constituted direct costs for a qualified non-hospital provider. Because of this uncertainty, the Secretary feared that apportioning costs between the hospital and the qualified non-hospital provider would result in double payments to the entities. However, this concern is not an issue when two hospitals split the costs of a medical residency training program because Medicare reimbursement for a teaching hospital's direct costs was based on a hospital-specific rate per resident and the hospital's number of full-time equivalent residents in training. 42 U.S.C. § 1395ww (1997). The Secretary did not address in the 1998 revised regulations a situation in which two or more hospitals split the total costs of a medical residency training program, with each hospital paying for the costs incurred in training its own residents. The Court finds that the 1998 revised regulations, as set forth in 63 Fed. Reg. 40,954 (July 31, 1998), did not in any manner establish a policy prohibiting hospitals from splitting the total costs of a medical residency training program.

b) 2003 AND 2007 REGULATIONS

In addition to relying on the 1998 revised regulations in his final decision, the Administrator found that the Preamble to the Federal Fiscal Year 2004 Inpatient Prospective Payment System final rule[9] and the Federal Fiscal Year 2008 Inpatient Prospective Payment System final rule[10] provided further clarification of the Medicare Act:

> The Preamble to the [Federal Fiscal Year] 2004 [Inpatient Prospective Payment System] final rule published in the Federal Register on August 1, 2003 offered

[9] Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2004 Rates, 68 Fed. Reg. 45,346 (Aug. 1, 2003).

[10] Medicare Program; Prospective Payment System for Long-Term Care Hospitals RY 2008: Annual Payment Rate Updates, and Policy Changes; and Hospital Direct and Indirect Graduate Medical Education Policy Changes, 72 Fed. Reg. 26,870 (May 11, 2007).

further explanation. The Secretary, in response to comments regarding the proposed rule, stated the following policy:

> [W]e believe that the statutory provisions cited above require hospitals to assume the cost of the full complement of residents training in the program at the non-hospital sites in order to count any [full-time equivalent] residents training at that site.

Subsequently, in the [Federal Fiscal Year] 2008 [Inpatient Prospective Payment System] rule, the Secretary addressed the existing policy in discussing the definition of "all or substantially all" costs and stated that:

> Global agreements with lump sum payment amounts, either for teaching physician costs or for non-hospital training in general, have not been sufficient under existing policy and would not be sufficient under the finalized policy. Similarly, as under current policy, if two (or more) hospitals train residents in the same accredited program, and the residents rotate to the same non-hospital site(s), the hospitals cannot share the costs of that program at that non-hospital site (for example, by dividing the [full-time equivalent] residents they wish to count according to some predetermined methodology), as we do not believe this is consistent with the statutory requirement at section 1886(h)(4)(E) of the Act which states that the hospital incur "all, or substantially all, of the costs for the training program in that setting."

See Docket No. 12, p. 10 (emphasis in original). The Administrator determined that neither of the Plaintiffs incurred all or substantially all of the costs for the full complement of the residents rotating through the Family Practice Center and, instead, shared the costs equally during the years 1999, 2000, and 2001. Accordingly, the Administrator found that the Plaintiffs did not meet the "all or substantially all" requirement under 42 U.S.C. § 1395ww(h)(4)(E) and 42 C.F.R. § 413.86(f)(4).

The Plaintiffs contend that the Secretary's 2003 interpretation of the Medicare Act, as stated in Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2004 Rates, 68 Fed. Reg. 45,346 (Aug. 1, 2003), was a substantive change in policy. The Plaintiffs contend that the retroactive application of the 2003 interpretation was arbitrary and

capricious. The Secretary contends that his 2003 interpretation is consistent with the 1998 revised regulations.

C. RETROACTIVE APPLICATION OF THE LAW

It is well-established that retroactivity is not favored in the law. The Court will not "retroactively apply statutes or regulations without a clear indication that the legislature or administrative agency intends to diverge from the norm of acting prospectively." Simmons v. Lockhart, 931 F.2d 1226, 1230 (8th Cir. 1991). "By the same principle, a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms." Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208 (1988). A statute operates retrospectively when it "'attaches new legal consequences to events completed before its enactment.'" Maitland v. Univ. of Minnesota, 43 F.3d 357, 362 (8th Cir. 1994) (quoting Landgraf v. USI Film Products, 511 U.S. 244, 270 (1994)). To make this determination, a court must consider "'the nature and extent of the change in the law and the degree of connection between the operation of the new rule and a relevant past event.'" Maitland, 43 F.3d at 362 (quoting Landgraf, 511 U.S. at 270).

The Medicare Act expressly prohibits the Secretary from enforcing a new policy retroactively:

> A substantive change in regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability under this subchapter shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that
>
> (i) such retroactive application is necessary to comply with statutory requirements; or

> (ii) failure to apply the change retroactively would be contrary to the public interest.

42 U.S.C. § 1395hh(e)(1)(A).

In this case, the regulation at issue, 42 C.F.R. § 413.86(f)(4) (2000), is modeled after, and nearly identical to, 42 U.S.C. § 1395ww(h)(4)(E) (2000) with the exception that the regulation imposes an additional requirement, namely, the written agreement requirement. In 1977, the Health Care Financing Administration was established to administer the Medicaid and Medicare programs. In 2001, the Health Care Financing Administration was renamed the Centers for Medicare and Medicaid Services (CMS). The Family Practice Center in Bismarck, North Dakota was established in 1976. During the tenure of the Family Practice Center, the Health Care Financing Administration and CMS were entrusted with the responsibility of administering the Medicare program.

Tim Blasl, the Patient Financial Services Coordinator at St. Alexius, testified before the Provider Reimbursement Review Board that prior to 2001, fiscal intermediaries consistently reimbursed Medcenter One and St. Alexius for the costs related to training their own residents, and did not require either hospital to incur all or substantially all of the costs for the entire residency training program:

> Q. [Counsel for the Plaintiffs]: So when you submitted the cost report for fiscal year 2001, did you have any reason to believe that the resident time that St. Alexis (sic) was going to claim for [the Family Practice Center] was going to be challenged by the Intermediary?
>
> A. [Blasl]: No, just based on 20 years of no adjustments, you know, I didn't expect that.

Q. [Counsel for the Plaintiffs]: When was the first time you heard the current position that only one hospital can claim the residents at a single non-hospital setting?

A. [Blasl]: I would say probably just a couple months ago.

Q. [Counsel for the Plaintiffs]: And had you heard in 2001 that St. Alexis (sic) couldn't claim residents at the Family Practice Center unless it incurred the costs of all residents there, would that have surprised you?

A. [Blasl]: Yes.

Q. [Counsel for the Plaintiffs]: And why is that?

A. [Blasl]: Just based on, you know, what happened before 2001 for, you know 15, 20 years.

Q. [Counsel for the Plaintiffs]: Had the Intermediary given or CMS given you some notice during or for fiscal year 2001 that one hospital had to claim all the residents rotating at the [Family Practice Center], what would you have done?

A. [Blasl]: Well, I would have sat down with both UND and Medcenter One and we would have been – we'd have gotten together to make sure we were in compliance. I mean, I think we would have been very proactive if we would have known about it.

. . .

Q. [Counsel for the Plaintiffs]: When did you hear of the current position that one hospital has to claim all residents at the [Family Practice Center], did you make any adjustments or take any actions relative to fiscal year 2001?

A. [Blasl]: Well, not to – you know, once we heard about it we actually were proactive and kind of had

> written agreements that stated that but, you know, it's a little late in the game because we're talking about 2001. We didn't find out until, you know, roughly December of '04 so it's hard to go back and fix that when we were told roughly in December of '04 . . . .

See Docket No. 12, pp. 99-100. Mike Harty, the Director of the Strategic Government Initiatives for Blue Cross Blue Shield Association,[11] confirmed that prior to the Secretary's 2003 interpretation, fiscal intermediaries allowed hospitals to share the costs of a residency training program. Mike Harty stated in an email to CMS:

> CMS policy states that since none of these hospitals have incurred "all or substantially all of the costs for the training program in the non-provider settings" then the [full-time equivalents] can not be counted at any of the hospitals. In 2003 CMS clarified this policy in the [Inpatient Prospective Payment System] proposed and final rule. Although CMS said this was only a clarification most if not all [fiscal intermediaries] were not applying this policy.

See Docket No. 12, p. 327.

The language of 42 C.F.R. § 413.86(f)(4) (2000) did not denote a change in practice, nor did it provide substantial notice of a policy change, to require Medcenter One or St. Alexius to incur all or substantially all of the costs for the entire residency training program at the Family Practice Center. Nor did the 1998 revised regulations, published at 63 Fed. Reg. 40,954 (July 31, 1998), provide such notice because the regulations related to the requirements of qualified non-hospital providers receiving compensation.

The first time that the Secretary published his intent to require a single hospital to incur the costs for the full complement of residents was in 2003 in the Medicare Program; Changes to the

[11] The Blue Cross Blue Shield Association handles the largest percentage of appeals for individual intermediaries nationwide for CMS. See Docket No. 12, p. 39.

Hospital Inpatient Prospective Payment Systems and Fiscal Year 2004 Rates, 68 Fed. Reg. 45,346, 45,450 (Aug. 1, 2003):

> [W]e believe the statutory provisions cited above require hospitals to assume the cost of the full complement of residents training in the program at the nonhospital sites in order to count any [full-time equivalent] residents training at that site.

In addition, the comments in the 2003 revised regulations confirm that the public believed a policy requiring a single hospital to incur the costs for the full complement of residents training in a residency training program was a change in policy:

> Comment: Several commentators objected to the sentence in the preamble to the proposed rule that stated: ". . . a hospital is required to assume financial responsibility for the full complement of residents training in a nonhospital site in a particular program in order to count any [full-time equivalent] residents training there for purposes of IME." One commenter explained that there are a number of situations where a hospital is truly incurring the cost of having a resident at a site, but the hospital is not incurring the cost of the entire complement of residents. "For example, if two different hospital programs each elect to send residents to the same clinic, under the interpretation in the [proposed rule], neither of the two hospitals would be able to count any of the residents because neither of the two programs would incur the cost of the full complement of residents." Another commenter believed that "this change" runs contrary to other current Medicare policies that focus on the resident rather than the program. The commenter believed that both the direct GME and IME regulations "are replete with references to 'resident' rather than 'program'." The commenter believed that "residency program" is referenced only in the context of the requirement that, for residents to be counted for direct GME and IME payments, they must be part of an "approved program" (§413.86(f)(1)).
>
> Response: We understand the concerns of the commenters about the requirement for a hospital to incur "all or substantially all of the cost" of training residents in a training program at a nonhospital site. However, we do not believe this is a change in policy. We believe that the policy that requires a hospital to incur the cost of "the program" in the nonhospital site has existed since the passage of the direct GME provisions, section 9314 of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99-509), and the passage of the IME provision, section 4621(b)(2) of the Balanced Budget Act of 1997 (Pub. L. 105-33), that permitted hospitals to continue to count residents in nonhospital sites, for purposes of direct GME and IME payment, if the hospital incurred "all or substantially all of the cost" of residents training in the

> program. As we explained in the proposed rule, this policy is derived from the language of the IME and direct GME provisions of the statute on counting residents in nonhospital settings . . . . Therefore, we believe a better reading of this language is that hospitals must incur all or substantially all of the cost for the full complement of residents in the training program at the nonhospital site.
>
> We note that the policy that requires the hospital to incur the cost of the program does appear to be somewhat of a departure from other current Medicare policies on graduate medical education that focus on the resident rather than the program, as the commenter suggests. However, we believe the statutory provisions cited above require hospitals to assume the cost of the full complement of residents training in the program at the nonhospital sites in order to count any [full-time equivalent] residents training at that site.

68 Fed. Reg. at 45,449, 45,450 (emphasis added). The comments to the preamble clearly reveal the overall perception that the 2003 policy of requiring a hospital to incur all or substantially all of the costs for the full complement of residents training in a residency training program was a change or departure in the policy that had existed for years.

The Court finds that the Secretary's 2003 interpretation of the Medicare Act was a substantive change in policy from prior interpretations, was not a reasonable administrative interpretation, and its application to the auditing of the Plaintiffs' cost reports for the years 1999, 2000, and 2001 was retroactive. The Court's finding is supported by comments made by the Office of Financial Management (OFM) regarding changes to the fiscal year 2004 GME payments. The OFM expressed confusion as to whether hospitals seeking Medicare reimbursement for training residents must incur all or substantially all of the costs of the entire residency training program, or whether the hospitals must incur all or substantially all of the costs of training their own residents:

> [W]e suggest that either in this [Change Request] or a Federal Register, [Center for Medicare Management] give examples of how the providers/intermediaries should apply the requirement that "The hospital incurs all or substantially all of the costs for the training program in the non-hospital setting." It is not clear whether a hospital must incur all or substantially all the costs for "all" the residents training in a specific

> non-hospital setting before it can count "any" resident in that setting. For example, each of two hospitals rotates five (5) residents to a physicians' private practice and those 10 residents are the only residents working at this non-hospital site. Each hospital pays the salaries and fringe benefits of five residents and appropriate portion of the teaching physician's compensation related to those residents. Does this mean that neither hospital can include the residents working at the physicians' private practice in their GME/IME count? Based on an explanation we obtained from [Center for Medicare Management], the requirement that the hospital "incurs all or substantially all [] of the costs of the training program in the non-hospital setting" means that one of the hospitals would have to incur the costs related to all 10 residents working at the physicians private practice in order to include them in the GME/IME. However, 42 CFR 413.86(f)(4((ii) states that in order to count a resident, the written agreement between the hospital and non-hospital site must indicate that the hospital will incur the cost of the "resident's salary and fringe benefits while the resident is training in the non-hospital site" and the hospital is providing reasonable compensation to the non-hospital site for supervisory teaching activities. We could interpret this to mean that if the hospital is paying the salaries and fringe benefits and proportionate share of the teaching physicians' compensation for any number of residents training at the non-hospital site (e.g., 5 even if 10 residents work at that site), the hospital can include this number (5 in this case) of residents in its GME/IME count. It appears that some providers and [fiscal intermediaries] may be interpreting the regulations in this way and that is the reason for our suggestion to give examples [of] how to apply 42 CFR 413.86(f)(4)(iii).

See Docket No. 12, pp. 63-64.

The OFM's comments reveal that, prior to the publication of the 2003 interpretation, the Secretary had not provided notice that 42 C.F.R. § 413.86(f)(4)(iii) prohibits hospitals from sharing the costs of a medical residency training program. The public expressed that the 2003 interpretation was a change in policy.

More important, prior to 1999, fiscal intermediaries, acting as agents on behalf of the Secretary, consistently allowed Medcenter One and St. Alexius to share the costs of the residency training program at the Family Practice Center and reimbursed the hospitals for the costs incurred in training their own residents. The well-established policy of fiscal intermediaries prior to the publication of the 2003 interpretation was to allow hospitals to share the costs of a medical residency

training program. Accordingly, the Court finds that the Secretary's 2003 interpretation of the Medicare Act was a significant and substantive change of policy which was not a reasonable administrative interpretation. The retroactive application of the 2003 interpretation is inapplicable under the Medicare Act unless (1) the retroactive application is necessary to comply with statutory requirements or (2) a failure to apply the 2003 interpretation retroactively would be contrary to the public interest. See 42 U.S.C. § 1395hh(e)(1)(A).

1) STATUTORY REQUIREMENTS

The Plaintiffs contend that the retroactive application of the 2003 administrative interpretation of the Medicare Act to the Plaintiffs' cost reports for the years 1999, 2000, and 2001 was not necessary to comply with statutory requirements. The Medicare Act provided that "all the time so spent by a resident under an approved medical residency training program shall be counted towards the determination of full-time equivalency, without regard to the setting in which the activities are performed, if the hospital incurs all, or substantially all, of the costs for the training program in that setting." 42 U.S.C. § 1395ww(h)(4)(E) (2000). The language of the statute does not require that one hospital pay for and claim all of the residents in the training program. The Administrator determined the Secretary's interpretation of 42 U.S.C. § 1395ww(h)(4)(E), to require a hospital to incur the cost of the entire residency training program, was "reasonable." The Administrator did not find that the language of 42 U.S.C. § 1395ww(h)(4)(E) (2000) mandates the Secretary's interpretation. Since 1986, Congress has imposed an "all or substantially all" requirement on a hospital seeking reimbursement for the direct costs incurred in training residents in a medical residency training program. See H.R. Rep. No. 99-727, at 70 (1986). In 1997,

Congress imposed this same requirement on a hospital seeking reimbursement for the indirect costs incurred in training residents in a medical residency training program. See 42 U.S.C. § 1395ww(d)(5)(B)(iv) ("Effective for discharges occurring on or after October 1, 1997, all the time spent by an intern or resident in patient care activities under an approved medical residency training program at an entity in a nonhospital setting shall be counted towards the determination of full-time equivalency if the hospital incurs all, or substantially all, of the costs for the training program in that setting."). Prior to 1999, the Secretary has consistently allowed the Plaintiffs to split the number of residents participating in the Family Practice Center and has reimbursed them for the costs incurred in training their own residents. In other words, fiscal intermediaries, acting on behalf of the Secretary, have consistently reimbursed the Plaintiffs for the costs they incurred in training their residents at the Family Practice Center. A fiscal intermediary acts as the Secretary's agent for the purpose of auditing cost reports and determining the total amount of reimbursement owed by Medicare to the medical provider in a given fiscal year.

It is clear that the fiscal intermediaries' continued practice of reimbursing the Plaintiffs for the costs incurred in training their residents at the Family Practice Center establishes compliance on behalf of the Secretary towards interpreting the statute as allowing at least two hospitals to split the total costs of a medical residency training program. Despite consistently interpreting 42 U.S.C. §§ 1395ww(d)(5)(B) and 1395ww(h)(4)(E) in this manner, the Secretary erroneously stated in 68 Fed. Reg. at 45,449-50 that the 2003 interpretation was not a change in policy. The Secretary's inconsistency in interpreting 42 U.S.C. §§ 1395ww(d)(5)(B) and 1395ww(h)(4)(E) reveals that the language of the statutes is anything but clear. Accordingly, the Court finds that the language of the Medicare Act does not require a single hospital to pay for and claim all of the residents in a medical

residency training program. The administrative interpretation to the contrary is neither reasonable nor plausible.

2) PUBLIC INTEREST

The Plaintiffs also argue that there is no public interest to justify applying the 2003 interpretation of the Medicare Act to their 1999, 2000, and 2001 cost reports. The Court agrees. In 68 Fed. Reg. at 45,444-45, the Secretary stated that, in order for a hospital to be reimbursed for the direct and indirect costs of training residents in a medical residency training program, the hospital must incur all or substantially all of the costs for the full complement of residents in the training program at the non-hospital site. The Secretary did not address concerns with allowing more than one hospital to share in the total costs of the training program. The Secretary did note concerns of some hospitals gaming the system by including costs that either the community or the educational institution have bore. However, such concerns do not arise when two hospitals share the total costs of the medical residency program by splitting the number of residents and paying for the total costs incurred in training their own residents. The Court has not located, nor have the parties indicated, that there are public comments which directly address the Secretary's currently-expressed concerns regarding two or more hospitals sharing the total costs of a medical residency training program. The Court finds that the public interest is far better served by adhering to the Secretary's interpretation of the Medicare Act prior to 2003. This same interpretation was consistently adopted and implemented by the fiscal intermediaries in the field until 2003. The confusing and ill-advised "all or nothing" interpretation adhered to by the Secretary since 2003, serves no legitimate public interest.

D. ARBITRARY AND CAPRICIOUS

The Administrator decided that neither of the Plaintiffs incurred all or substantially all of the costs for the full complement of residents training at the Family Practice Center in 1999, 2000, and 2001. To reach this conclusion, the Administrator determined that "program," as set forth in 42 U.S.C. § 1395ww(h)(4)(E), refers to an "approved residency training program" and, therefore, a hospital must pay all or substantially all of the costs of the entire residency training program before it can claim any residents on its cost reports. The evidence reveals that, prior to 1999, fiscal intermediaries consistently allowed Medcenter One and St. Alexius to split the costs of the residency training program at the Family Practice Center. Moreover, the nationwide practice of fiscal intermediaries prior to the publication of the 2003 interpretation was to allow hospitals to share the costs of a medical residency training program for purposes of reimbursement. As previously noted, the fiscal intermediaries are agents of the Secretary of the Department of Health and Human Services.

The Secretary's proposed definition of "program" is inconsistent with the Secretary's prior practice of allowing hospitals to share the costs of a medical residency training program. In addition, the legislative history of 42 U.S.C. § 1395ww(h)(4)(E) indicates that Congress clearly intended to encourage hospitals to train residents in non-hospital sites. Even the Secretary acknowledged that, by enacting legislation reimbursing hospitals for non-hospital residency training, "Congress intended to create a monetary incentive for hospitals to rotate residents from the hospital to the nonhospital settings." Medicare Program, 68 Fed. Reg. at 45,436. Under the Administrator's interpretation of "program," only one hospital could claim residents training at a non-hospital setting. This restriction disproportionately places the financial burden on one hospital to incur the costs of a residency

training program even if residents from other hospitals are training in the program. As a result, the Administrator's prohibition of allowing more than one hospital to share the costs for training residents deters hospitals, particularly rural hospitals, of training residents in non-hospital settings. Such an interpretation is neither reasonable nor fair.

In addition, the purpose of the legislation was to expand the Medicare Act to ensure that hospitals were reimbursed for residency training "without regard to the setting in which the activities are performed." 42 U.S.C. § 1395ww(h)(4)(E). There is no indication that the purpose of the legislation was to change the payment structure that had already existed under the Medicare Act and existing regulations. Pursuant to 42 U.S.C. § 1395ww(h)(4)(E) and 42 C.F.R. § 412.105, Medicare reimbursement is determined on a per-resident amount. The Secretary first provided notice prohibiting hospitals from sharing the costs of a medical residency program in 68 Fed. Reg. 45,346 (Aug. 1, 2003). The retroactive application of the 2003 interpretation to the Plaintiffs' 1999, 2000, and 2001 cost reports was arbitrary and capricious. Accordingly, the Court expressly finds that the Administrator's decision was arbitrary and capricious.

IV. CONCLUSION

The Court finds that the Secretary's 2003 interpretation of the Medicare Act was a significant change in policy. There is no exception, either statutorily or on public policy grounds, which warrants a retroactive application of the 2003 interpretation to the Plaintiffs' 1999, 2000, and 2001 cost reports. Accordingly, the Court finds that the Administrator's application of the 2003 interpretation to the Plaintiffs' 1999, 2000, and 2001 cost reports was arbitrary and capricious. The Administrator's decision is implausible and reversed.

The Court further finds that the decision of the Provider Reimbursement Review Board was correct, was in conformance with the law, and should be upheld. The Court incorporates by reference the specific findings of fact, conclusions of law, and legal discussion as set forth in the Review Board's decision. A careful de novo review of the entire administrative record leads this Court to conclude that common sense, fairness, and a reasonable interpretation of the Medicare Act warrant this conclusion.

The Plaintiffs' motion for summary judgment (Docket No. 15) is **GRANTED** and the Defendant's motion for summary judgment (Docket No. 21) is **DENIED**. The Court orders that judgment be entered on behalf of the Plaintiffs for all direct and indirect costs disallowed by the Secretary for the fiscal years 1999, 2000, and 2001, inclusive, plus interest.

IT IS SO ORDERED.

Dated this 13th day of October, 2009.

/s/ Daniel L. Hovland
Daniel L. Hovland, Chief Judge
United States District Court